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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|----------------------------------|-----------------|----------------------|-------------------------|------------------|
| 09/848,095 | 05/03/2001 | Jay M. Short | DIVER1280-10 | 7088 |
| 7 | 7590 06/30/2003 | | | O.U.D. |
| Lisa A. Haile, Ph.D. | | | EXAMINER | |
| GRAY CARY WARE & FREIDENRICH LLP | | | KETTER, JAMES S | |
| Suite 1100 4365 Executive Drive | | | ART UNIT | PAPER NUMBER |
| San Diego, CA 92121-2189 | | | 1636 | 21 |
| | | | DATE MAILED: 06/30/2003 | 3 |

Please find below and/or attached an Office communication concerning this application or proceeding.



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| APPLICATION NO./ CONTROL NO. | FILING DATE | FIRST NAMED INVENTOR / PATENT IN REEXAMINATION | | ATTORNEY DOCKET NO. |
|------------------------------|-------------|--|----------|---------------------|
| | | | | EXAMINER |
| | | | ART UNIT | PAPER |

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Commissioner for Patents

21

--See attached--

| | | Application No. | Applicant(s) |
|--|--|--|--|
| • | · . | 09/848,095 | SHORT ET AL. |
| Office Action Summary | | Examiner | Art Unit |
| | 2 | James S. Ketter | 1636 |
| | The MAILING DATE of this communication ap | pears on the cover sheet v | |
| Period fo | r Reply | | |
| THE N - Exter after - If the - If NO - Failu | ORTENED STATUTORY PERIOD FOR REPL MAILING DATE OF THIS COMMUNICATION. nsions of time may be available under the provisions of 37 CFR 1. SIX (6) MONTHS from the mailing date of this communication. I period for reply specified above is less than thirty (30) days, a repulp period for reply is specified above, the maximum statutory period reply within the set or extended period for reply will, by statutively received by the Office later than three months after the mailing apparent term adjustment. See 37 CFR 1.704(b). | 136(a). In no event, however, may a sly within the statutory minimum of the will apply and will expire SIX (6) MC or cause the application to become | reply be timely filed irty (30) days will be considered timely. NTHS from the mailing date of this communication. ABANDONED (35 U.S.C. § 133). |
| Status 1)⊠ | Responsive to communication(s) filed on 22 | <u>May 2003</u> . | |
| 2a)⊠ | | his action is non-final. | |
| 3)□ | Since this application is in condition for allow | vance except for formal m | atters, prosecution as to the merits is |
| , | closed in accordance with the practice under ion of Claims | r Ex parte Quayle, 1935 (| C.D. 11, 453 O.G. 213. |
| | Claim(s) 1,2,7-18,20-28,33-44 and 47-55 is/a | are pending in the applica | tion. |
| | 4a) Of the above claim(s) is/are withdra | | |
| 5)□ | Claim(s) is/are allowed. | | |
| 6)⊠ | Claim(s) <u>1,2,7-18,22-28,33-44 and 50-55</u> is/a | re rejected. | |
| | Claim(s) 20, 21 and 47-49 is/are objected to. | | |
| | Claim(s) are subject to restriction and/ | or election requirement. | |
| • • | tion Papers | | |
| 9)[| The specification is objected to by the Examin |)er. | y the Evaminer |
| 10) | The drawing(s) filed on is/are: a)☐ acc | epted or b) objected to b | y the Examiner. Evance See 37 CFR 1.85(a). |
| 4 4 K 7 | Applicant may not request that any objection to the proposed drawing correction filed on 27 A | uie drawing(s) be lield in ab ∆ugust 2002 is: a\⊠ abbi | oved b) disapproved by the Examiner. |
| 11)⊠ | The proposed drawing correction filed on <u>27 F</u> If approved, corrected drawings are required in the second | | |
| 40\F7 | The oath or declaration is objected to by the E | | |
| | | | |
| | under 35 U.S.C. §§ 119 and 120 Acknowledgment is made of a claim for forei | ian priority under 35 U.S. | C, § 119(a)-(d) or (f). |
| |) | .g p aa | |
| a ' | . The second of the second of the decision | ents have been received. | |
| | 1. Certified copies of the priority docume2. Certified copies of the priority docume | | Application No |
| | 3. ☐ Copies of the certified copies of the pr | iority documents have be | en received in this National Stage |
| * | application from the International It See the attached detailed Office action for a li | Bureau (PCT Rule 17.2(a ist of the certified copies r |)). not received. |
| | Acknowledgment is made of a claim for dome | | |
| 15) | a) The translation of the foreign language packnowledgment is made of a claim for dome | provisional application ha estic priority under 35 U.S | s been received. .C. §§ 120 and/or 121. |
| Attachme | ent(s) | _ | |
| 2) No | tice of References Cited (PTO-892) tice of Draftsperson's Patent Drawing Review (PTO-948) ormation Disclosure Statement(s) (PTO-1449) Paper No(s | 5) Notice | ew Summary (PTO-413) Paper No(s) e of Informal Patent Application (PTO-152) . |
| LLC Patent and | d Trademark Office | | |

Art Unit: 1636

In response to the Notice to Comply with Requirements for Patent Applications

Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures, attached to paper
no. 13, mailed 19 November 2002, Applicants have requested, in Paper No. 16 filed 25 April
2003, that the CRF, sequence amendment and statement that the two are the same, be transferred
from the parent application. As noted in the Advisory Action mailed 9 May 2003, however, only
the CRF may be thus transferred. Applicants response of 25 April 2003 appears bona fide, and
as such, the time period of the instant Office Action is set as the time period for response. See
the new Notice to Comply, attached. Any response to this Office Action which fails to comply
with all the remaining requirements under the sequence rules, 37 CFR §§ 1.821-1.825, those
requirements being the need for a sequence amendment and a letter stating that the contents of
the CRF and the sequence amendment are the same, will be held non-responsive.

Claims 20, 21 and 47-49 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 2, 7-10, 16-18, 23-28, 33-36, 39-44 and 51-53 stand rejected under 35 U.S.C. 102(e) as being anticipated by Thompson et al. (US Patent 5,824,485) for reasons of

Art Unit: 1636

record set forth in Papers Nos. 5, 13 and 17, mailed 20 February 2002, 19 November 2002 and 9 May 2003, respectively.

Applicants' arguments in the amendment after final filed 25 April 2003 were addressed in the advisory action mailed 9 May 2003. Applicants have amended some of the claims in the amendment filed 22 May 2003, but have offered no further arguments.

It is noted that claim 1, as now amended, has another step, now designated "b)", drawn to the step of transferring a plurality of the clones to a myceliate bacteria or fungi. However, it is noted that Thompson et al. teaches the use of 2 <u>Streptomyces</u> species, <u>Neurospora crassa</u> or <u>Aspergillus nidulans</u> as host cells for the clones, e.g., at column 18, lines 45-59. As such, the instant claims remain anticipated by Thompson et al.

Claims 1, 2, 7-18, 23-28, 33-44 and 51-53 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Thompson et al. ('485) in view of Plovins et al. and Zhang et al. for reasons of record set forth in Papers Nos. 5, 13 and 17, mailed 20 February 2002, 19 November 2002 and 9 May 2003, respectively.

Applicants' arguments in the amendment after final filed 25 April 2003 were addressed in the advisory action mailed 9 May 2003. Applicants have amended some of the claims in the amendment filed 22 May 2003, but have offered no further arguments.

It is noted that claim 1, as now amended, has another step, now designated "b)", drawn to the step of transferring a plurality of the clones to a myceliate bacteria or fungi. However, it is noted that Thompson et al. teaches the use of 2 <u>Streptomyces</u> species, <u>Neurospora crassa</u> or

Art Unit: 1636

Aspergillus <u>nidulans</u> as host cells for the clones, e.g., at column 18, lines 45-59. As such, the instant claims remain rejected over the grounds set forth above.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 7-18, 22-28, 33-44 and 50-55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 26, and therefore all claims dependent therefrom, have been amended to recite the phrase "a myceliate bacteria or fungi". However, it is not clear whether the term "myceliate" is meant to limit "fungi". As such the metes and bounds of the instant claims are unclear.

Furthermore, while not part of the rejection, it is noted that the article "a", which is singular, refers to "bacteria" or "fungi", which are plural. Applicants may wish to bring the number into grammatical agreement.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1636

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Certain papers related to this application may be submitted directly to the Examiner by facsimile transmission at (703) 746-5155. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993)(see 37 CFR ' 1.6(d)). To send the facsimile to the Art Unit instead, the Art Unit 1636 Fax number is (703) 305-7939. NOTE: If Applicant does submit a paper by fax to this number, the Examiner must be notified promptly, to ensure matching of the faxed paper to the application file, and the original signed copy should be retained by Applicant or Applicant's representative. (703) 308-4242 or (703) 305-3014 may be used without notification of the Examiner, with such faxed papers being handled in the manner of mailed responses. Applicant is encouraged to use the latter two fax numbers unless immediate action by the Examiner is required, e.g., during discussions of claim language for allowable subject matter. NO

Art Unit: 1636

DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the Examiner with respect to the examination on the merits should be directed to James Ketter whose telephone number is (703) 308-1169. The Examiner normally can be reached on M-F (9:00-6:30), with alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Remy Yucel, can be reached at (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Jsk June 25, 2003

> JAMES KETTER PRIMARY EXAMINER